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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,643	07/19/2000	Dane K. Fisher	38-21(51230)B	2183

7590 05/08/2002

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ART UNIT	PAPER NUMBER
1634	12

DATE MAILED: 05/08/2002

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 12

Application Number: 09/619,643
Filing Date: July 19, 2000
Appellant(s): FISHER ET AL.

Mailed 5/8/02

June E. Cohan (Reg. No. 43,741)
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 5, 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: the rejections under 102 for anticipation have been withdrawn for the reasons provided below.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

A) Walbot, Genbank Accession Number AI978199, August 1999

B) Walbot, Genbank Accession Number AI73448, February 2000.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf]

"Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring.

On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.

"Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

The claimed nucleic acid compounds are not supported by a specific asserted utility because the disclosed uses of the nucleic acids are not specific and are generally applicable to any nucleic acid. The specification teaches that the nucleic acids may be

used to produce a plant containing reduced levels of a protein (pg. 11), determining an association between a polymorphism and a plant trait (pg. 11), isolating a genetic region or nucleic acid (pg. 11), determining a level or pattern in a plant cell of a protein in a plant (pg. 11), determining a mutation in a plant whose presence is predictive of a mutation affecting a level or pattern of a protein (pg. 13), as molecular tags to isolate genetic regions, isolate genes, map genes, and determine gene function (pg. 14), and identifying tissues (pg. 14), The specification states that the nucleic acid ESTs of the present invention can enable the acquisition of molecular markers, which can be used in breeding schemes, genetic and molecular mapping and cloning of agronomically significant genes (pg. 31). These are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acids being claimed.

Further, the claimed nucleic acid compounds are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by applicant(s) to characterize potential protein

products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid compounds such that another non-asserted utility would be well established for the compounds.

Response to Arguments

The Appellant traverses the rejection. The Appellant asserts the utility guidelines have been satisfied by at least the ability to use the claimed nucleic acid to "identify the presence or absence of a polymorphism, and use as a hybridization probe for expression profiling" (page 5, para 2 of brief). The Appellant also asserts additional utilites for the claimed nucleic acid molecules "including introduction of the claimed nucleic acid molecules into a plant or plant cell which can then be used to screen for compounds such as a herbicide (page 6, lines 1-4 of brief).

Each of these asserted utilities has been thoroughly considered, but not been persuasive. All of these additional asserted utilities fail to meet the utility guidelines in so much as they are not specific or substantial. As stated above, a "Specific Utility" is a utility that is *specific* to the subject matter claimed. A general

statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Moreover, "Substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. Thus, these additional utilities also do not meet the guidelines. Identifying the presence or absence of a polymorphism and functioning as a hybridization probe for expression profiling are general utilities for which every nucleic acid could be used. Similarly, using the nucleic acid to transfect a plant for the screening of compounds is not a specific and substantial utility until such a compound has in fact been identified.

The Appellant argues that cell-based assay screens have utility and the screen of a plant or plant cell having a nucleic acid as instantly claimed is a legally sufficient utility. The Appellant points to a cite in the MPEP 2107 at page 2100-25. However, the Examiner is unable to locate any such proposition at this cite or in the MPEP as a whole. Cell-based assay screens are a very broad term which implies any assay which relies upon cells such as in situ hybridization or in vitro amplification. These assays have separate utility analysis and therefore, to conclude generically that cell-based assays have utility is a generalization. That is, while a cell based assay could be a specific and substantial utility if the assay was being used to determine a particular condition or disease, for example, cell based assays in general are again a general use for nucleic acids for which any nucleic acid could be used.

The Appellant also argues that measuring the level of mRNA in a sample is a sufficient utility. Footnote 3 on page 6 is an accurate analysis of the art. However the analysis is not analogous to the instant situation. The analysis provides detecting expression changes in traits of interest such as drought stress. The instant application has not provided any such analysis of the level of mRNA in a sample as compared to a trait of interest. In the event that the detection of change in level of mRNA in a sample were indicative of a trait, the claimed nucleic acids would likely have a specific and substantial utility. As provided by the Utility Guidelines, substantial utility is not present when A.) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved. B.) A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.) C.) A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility". Appellants appear to be arguing that the instant nucleic acid sequences may be attached to a microarray for further study of the material to determine whether changes in the expression are indicative of a trait of interest. Therefore, the instant claimed nucleic acids appear to require further experimentation on the material itself to determine the function and properties of the claimed nucleic acids.

Moreover, Appellant argues that use as a molecular marker is a patentable utility. This argument has been thoroughly reviewed, but like the proposed utilities above, the utility of the instant nucleic acids as a molecular marker fails to meet substantial utility

because the proposed utilities are basic research such as studying the properties of the claimed product, i.e. the position of the nucleic acid in the scheme of the maize genome or the mechanisms in which the material is involved, i.e. the particular traits which the marker is associated.

Specifically, "identifying the presence or absence of a polymorphism" (page 6 of brief) is not considered a substantial utility because the proposed utility is merely determining and studying the properties of the claimed nucleic acid. As provided by As noted by Brenner v. Manson, 383 U.S. 519, 535-536 (1996), "Congress intended that no patents be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing...a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". The identification of the presence of absence of a polymorphism is strictly speaking a hunting license which requires further research to obtain the presence of a polymorphism. Furthermore, even if the polymorphism is determined, the presence or absence of a polymorphism does not have a clear utility. Polymorphisms are natural variations within sequences which themselves may not have any meaningful use. Therefore, determining whether the claimed nucleic acids have or do not have a polymorphism would require determining whether there was a polymorphism within such a sequence and then determining how to use this information in a patentably meaningful way. The Appellant also argues, "many of these uses are directly analogous to a microscope". This argument has been reviewed but is not convincing because the microscope provides information to the scientist which is automatically useful. For example, the microscope may be used for

identification and differentiation between gram-positive and gram-negative bacteria. The differentiation of bacteria facilitates in the administration of proper antibiotics. For example, if the microscope is used to determine whether Staph is present or whether Strep is present provides valuable information to the scientist and/or doctor for treating patients. The instant invention, however, provides no information to this extent. If the scientist determines that SEQ ID NO: 1 is present, the scientist does not know how to use this information. Thus, the identification of SEQ ID NO: 1 is not a substantial utility.

With respect to "probes for other molecules or source for primers", Appellant's argue that the claimed nucleic acid molecules may be used to isolate the promoter of the gene by initiating a chromosome walk (page 8, para 3 of the brief). Once again, this proposed utility requires performing research on the claimed nucleic acids to further research the properties. The Appellant argues the asserted utilities are not insufficient because other molecules can be used for the same purpose. This argument has been reviewed but is not convincing because the guidelines specifically state that a specific utility" is a utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. With regard to Appellants arguments directed to new golf clubs which are used for the same purpose such as hitting golf balls, in that particular example, the new golf clubs would be specific to the intended use of hitting golf balls. The instant nucleic acids are more closely related to the idea that not every piece of sports equipment would be applicable to this use, i.e. golf gloves. The guidelines do not prohibit multiple products with the same utility, i.e. exclusive utility. The guidelines are directed to knowing how to use the

instant nucleic acids in a specific manner. For example, a large group of nucleic acids provide information with respect to predisposition to diabetes. This is considered to be specific and substantial utility. The nucleic acid is not required to be the only nucleic acid which has a certain utility. However, in the instant case the claims are drawn to nucleic acids which have the assertion of being applicable to things in which every nucleic acid is applicable such as molecular tags to isolate genetic regions. With respect to Appellants arguments that the claimed nucleic acid molecules will identify a unique subset of related sequences, the guidelines specifically state, "A method of assaying for or identifying a material that itself has no "specific and/or substantial utility" does not have specific and substantial utility. Since the unique subset of related sequences has no utility, this provides no support for utility. The use of the claimed nucleic acids to obtain and isolate a promoter that is active in leaves at the time of anthesis is part of the research, and not a successful completion of the research. The artisan would be required to provide additional analysis to obtain a useful result for the claimed nucleic acids.

Thus, in summary, the instant EST nucleic acids do not have a substantial or specific utility. Each of the provided utilities is general, as provided in the Utility Guidelines.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

The Appellant traverses the rejection. The Appellant asserts that the rejection under utility has been overcome by the foregoing arguments. This argument has been reviewed but is not convincing because the arguments provided above were not persuasive. Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence selected from SEQ ID NO: 1-5.

The specification teaches the nucleic acid of SEQ ID NO: 1-5.

There is not adequate description of the genus of nucleic acids comprising SEQ ID NO: 1-5. The specification only discloses nucleic acids of SEQ ID NO: 1-5. The claim is drawn to a genus which includes any nucleic acid which minimally contains SEQ ID NO: 1-5. The claim encompasses genes, full open reading frames, fusion constructs, and cDNAs. There is substantial variability among the species of DNAs encompassed within the cope of the claims because SEQ ID NO: 1-5 is only a fragment of any full-length gene of cDNA species. The nucleic acids described are not representative of the genus nucleic acids comprising SEQ ID NO: 1-5. Furthermore, one of skill in the art would conclude that applicant was not in possession of the claimed "nucleic acids comprising SEQ ID NO: 1-5" because the description of only five members of this genus is not representative of the nucleic acids of the genus and is insufficient to support the claims. Weighing all factors,

1) partial structure of the DNAs that comprise SEQ ID NO: 1-5;

2) the breadth of the claim as reading on genes yet to be discovered in addition to numerous fusion constructs and cDNAs

3) the lack of correlation between the structure and the function of the genes and/or fusion constructs; in view of the level of knowledge and skill in the art, one skilled in the art would not recognized from the disclosure that the applicant was in possession of the genus of DNAs which comprise SEQ ID NO: 1-5. Thus, the specification does

not adequately provide a written description for nucleic acids comprising SEQ ID NO: 1-5.

Response to Arguments

The Appellant traverses the rejection. The Appellant asserts that Appellants need not "describe," all things that are encompassed by the claims. This argument has been reviewed but is not convincing for the reasons specifically set out in the Written Description guidelines, Example 7, directed to ESTs. The Written Description guidelines, specifically provide that a description of a genus of cDNAs may be achieved by means of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Appellants have provided one member of the genus of nucleic acids comprising SEQ ID NO: 1, namely SEQ ID NO: 1. This is not considered to be a substantial portion of the genus. The genus includes genes yet to be discovered which have not been described. It is noted *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Appellant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written

description of the genus. The court indicated that while Appellants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of specifies have been described by their complete structure. In the instant case, Appellant has defined only a fragment of a nucleic acid sequence. Appellant has not disclosed any genomic DNA sequences and particularly has not disclosed any intron sequences or regulatory sequences. Accordingly, Appellants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

Thus for the reasons above and those already of record, the rejection is maintained.

***Withdrawal* of Claim Rejections - 35 USC § 102**

The rejections under 35 U.S.C. 102(a) as being anticipated by Walbot-1 (Genbank Accession Number AI978199, August 1999) and Walbot-2 (Genbank Accession Number AI734448, February 2000) have been withdrawn.

While Walbot-1 and Walbot-2 teach nucleic acids which are substantially identical to the claimed nucleic acid of 333 base pairs in length, the nucleic acids of Walbot-1 and Walbot-2 are not identical to SEQ ID NO: 5. Walbot-1 contains a single mismatch at position 63 of SEQ ID NO: 5 (within a region of high GC content). Walbot-2 contains two mismatches at position 35 and 63 of SEQ ID NO: 5. Upon translation of the nucleic acid of SEQ ID NO: 5 and the translation of the nucleic acid in the art, the nucleic acids contain numerous stop codons. It is noted that the instant SEQ ID NO: 5, translated in all of the 6 possible frames does not appear to code for a full protein since each of the possible translations do not contain a start codon, and moreover, contain numerous stop codons which terminate the translation of the protein. See attached translations for SEQ ID NO: 5 as well as the two nucleic acids in the art. For example, frame 1 of SEQ ID NO: 5 begins with two stop codons and frame 2 contains a stop codon at the 16^{th} amino acid.

(11) Response to Argument

Each of Appellant's arguments have been discussed in detail in the prior section. For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Jeanine Goldberg
April 23, 2002

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; Entered [bobryen 28-Feb-02 15:41]

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;             clade; Panicoideae; Andropogoneae; Zea.
; REFERENCE   1  (bases 1 to 582)
;   AUTHORS   Walbot,V.
;   TITLE     Maize ESTs from various cDNA libraries sequenced at Stanford
;             University
;   JOURNAL   Unpublished (1999)
; COMMENT     Contact: Walbot V
;             Department of Biological Sciences
;             Stanford University
;             855 California Ave, Palo Alto, CA 94304, USA
;             Tel: 650 723 2227
;             Fax: 650 725 8221
;             Email: walbot@stanford.edu
;             Plate: 606031  row: E  column: 07.
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;
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;             mRNA sequence.
; ACCESSION   AI978199
; VERSION     AI978199.1  GI:5791407
; KEYWORDS    EST.
; SOURCE      Zea mays.
;   ORGANISM  Zea mays
;             Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
;             Spermatophyta; Magnoliophyta; Liliopsida; Poales; Poaceae; PACC
;             clade; Panicoideae; Andropogoneae; Zea.
; REFERENCE   1  (bases 1 to 442)
;   AUTHORS   Walbot,V.
;   TITLE     Maize ESTs from various cDNA libraries sequenced at Stanford
;             University
;   JOURNAL   Unpublished (1999)
; COMMENT     Contact: Walbot V
;             Department of Biological Sciences
;             Stanford University
;             855 California Ave, Palo Alto, CA 94304, USA
;             Tel: 650 723 2227
;             Fax: 650 725 8221
;             Email: walbot@stanford.edu
;             Plate: 614041  row: D  column: 10.
; FEATURES             Location/Qualifiers
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;                      /cultivar="W23"
;                      /db_xref="taxon:4577"
;                      /clone_lib="614 - root cDNA library from Walbot Lab"
;                      /tissue_type="root"
;                      /dev_stage="3-4 days old"
;                      /lab_host="XLOLR"
;                      /note="Organ: root; Vector: pBlueScriptII SK+; Site_1:
;                      EcoRI; Site_2: XhoI; 3-4 days old root tissue from Walbot
;                      Lab (LM)"
; BASE COUNT      126 a    107 c     93 g    116 t
; ORIGIN
;
;  AI978199  Length: 442  February 28, 2002 15:33  Type: N  Check: 48  ..
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AI978199_2
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AI978199_5
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